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10/524,867	02/14/2005	Amram Eizenfeld	415/14	2989
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Sean Liam Kelleher Kelleher & Lilling PLLC P.O. BOX 560 GOLDEN BRIDGE, NY 10526			EXAMINER	
			NIA, ALIREZA	
			ART UNIT	PAPER NUMBER
			3739	
			NOTIFICATION DATE	DELIVERY MODE
			05/30/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sean@lilling.com

Office Action Summary

Application No.

10/524,867

Applicant(s)

EIZENFELD ET AL.

Examiner

ALIREZA NIA

Art Unit

3739

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Two consecutive sets of claims were numbered as claim 49 (such as: 48, 49, 49, 50,...).
2. Misnumbered claims 49-69 have been renumbered claims 50-70. **As a result, claims 48-70 are now pending in the application.** Claim 51 (originally designated as claim 50) now depends from claim 50. Claims 53 and 54 (originally designated as claims 52 and 53) depend from claim 52. Claim 55 (originally designated as claim 54) depends from claim 54. Claim 57 (originally designated as claim 56) now depends from claim 56. Claim 59 (originally designated as claim 58) now depends from claim 58. Claims 60 and 61 (originally designated as claims 59 and 60) now depends from claim 54. Claims 64-67 and 69 (originally designated as claims 63-66 and 68) now each depend from independent claim 63 (originally designated as claim 62). Claim 68 (originally designated as claim 67) now depends from claim 67. Claim 70 (originally designated as claim 69) now depends from claim 69.
3. Claims 52 and 56 are objected to because of the following informalities: the term -- claim -- is missing before the numbers "48" for showing claim dependency. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 60 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 60 and 61 recite the limitations "the insertion tube" in lines 2 of both claims. There is insufficient antecedent basis for this limitation in the claim. Claims 60 and 61 are examined as best understood.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 48, 49, 56, 62-64, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiore 3,421,509 in view of Szabo 5,325,846.**
8. With respect to claim 48 and 63-64, Fiore '509 discloses an apparatus 20,32 for sheathing a flexible endoscope 10 during insertion of the endoscope 10 into a body passage, said apparatus comprising a dispenser 20,32 having entry 23 and exit 26 ports defining a transit passage 24 through which the endoscope 10 may pass in a distal direction, and said dispenser being placed so that the exit port 26 is adjacent to said body passage of a patient, a flexible sleeve 28,36 at least a portion of which is bunched in a vicinity of the exit port 26 of said dispenser 20,32, an open proximal end being fixed to and within the dispenser 20,32 via 29, wherein the endoscope

10 entering into the flexible sleeve 20,32 through the proximal end 23 of the dispenser 20,32 and engaging the distal end of the flexible sleeve 28,36, the bunched portion of the flexible sleeve 28,36 being extended to cover at least a distal part 13 of the endoscope 10 that protrudes through the exit port 26, the distal part 13 of the endoscope 10 covered by the flexible sleeve 28,36 extending into said body passage of the patient, the bunched portion of the flexible sleeve 28,36 being adjacent to the distal end of the flexible sleeve 28,36, and the flexible sleeve 28,36 extending away from the bunched portion in a proximal direction so as to cover the endoscope 10 as it is advanced, and a capture mechanism 29,30 in said dispenser 20,32 to capture the flexible sleeve 28,36 as the endoscope is retracted through the transit passage 24 in the proximal direction, wherein the flexible sleeve 28,36 being removed from a proximal part of the endoscope that has been retracted through the entry port and the captured flexible sleeve being gathered in the dispenser (figs. 1-5, col. 2, lines 23-72, cols. 3-5, lines 1-75). Fiore '509 also discloses inserting a distal part of the endoscope 10 into the proximal end and through a bunched portion of the flexible sleeve 28,36 to engage the distal end via 20, advancing the endoscope 10 through a body opening of a patient into a body passage, unfolding the flexible sleeve 28,36 from the a region to cover the distal part of the endoscope 10, and extending the bunched portion of the flexible sleeve to cover the distal part of the endoscope 10 that extends through the body opening into the body passage, and capturing the flexible sleeve 28,36 via 29,30 via retracting the endoscope 10 in a proximal direction, the flexible sleeve 28,36 being capable of being removed from a proximal part 12 of the endoscope and gathering in allocation adjacent to the body opening (outside of the endoscope). Fiore '509 discloses the receptacle 20 which is

capable of capturing the flexible sleeve 28,36 by gathering substantially all of the flexible sleeve 28,36 within receptacle 20.

9. However, Fiore '509 fails to positively disclose the flexible sleeve comprises a closed distal end and an open proximal end. Fiore '509 also fails to positively disclose bunching at least a portion of the flexible tube in a compaction region.

10. Szabo teaches an analogous apparatus A for sheathing and endoscope comprising a flexible sleeve 22, at least a portion of which is bunched in a vicinity of an exit port in a compaction region 17 of said dispenser, the flexible sleeve 22 comprising a closed distal end 34 an open proximal end 18 (col. 3, lines 25-68, col. 4, lines 1-55, fig. 1), resulting in an improved endoscopic draping system that allows operating room personnel to easily and expeditiously drape an endoscope (col. 2, lines 34-35).

11. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the apparatus for sheathing a flexible endoscope of Fiore '509 with the above discussed limitations as taught by Szabo in order to have provided an improved endoscopic draping system that allows operating room personnel to easily and expeditiously drape an endoscope which ensures a streamlined fit allowing the surgeon greater maneuverability and less bulk while eliminating slippage.

12. With respect to the methods and steps recited in claims 63-64 and 67, where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

13. With respect to claim 49, Fiore '509 in view of Szabo discloses the invention as discussed above. Fiore '509 further teaches that the apparatus for sheathing a flexible endoscope is capable of, after the distal part of the endoscope 10 has been retracted through the entry port, to contain substantially all of the flexible sleeve 28,36 within the dispenser 20,32.

14. With respect to claims 56 and 67, Fiore '509 in view of Szabo discloses the invention as discussed above. Fiore '509 further teaches a working channel 14 extending along the endoscope 10, the working channel 14 comprising distal 13 and proximal 12 extremities, wherein the distal extremity 13 being fixed to the distal end of the flexible sleeve 28,36 and the proximal extremity being protruding from the dispenser 32,34 (figs. 4,5).

15. With respect to claim 62, Fiore '509 in view of Szabo discloses the invention as discussed above. Fiore '509 further teaches the capture mechanism 29,30 is an anchor 30 (for 29) (fig. 4).

16. Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiore 3,421,509 in view of Szabo 5,325,846 further in view of Hicks 5,198,894.

17. Fiore '509 in view of Szabo discloses the invention as discussed above. Szabo further discloses a dispenser A comprises a proximal section 18 defining the entry port and to which the flexible sleeve 22 is fixed.

18. However, Fiore '509 in view of Szabo fails to positively disclose a distal section defining the exit port and to which the external sleeve is fixed.

19. Hicks teaches an analogous endoscopic draping system comprising a distal section 18 defining an exit port and to which an external sleeve 22 is fixed (fig. 2), resulting in an improved endoscope structure which allows an observation portion to be secured to a proximal end of an

endoscope in a sterile environment at a location where the endoscope exits the body cavity (col. 1, lines 6-10).

20. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the endoscopic draping system of Fiore '509 in view of Szabo with the above discussed limitations as taught by Hicks in order to have provided improved endoscope structure which allows an observation portion to be secured to a proximal end of an endoscope in a sterile environment at a location where the endoscope exits the body cavity, mitigating the need to re-sterilize the observation section of the endoscope after each surgery, facilitating a low-cost and quick turnaround of an operating room within an outpatient surgical center.

21. Claims 52-55, 60, 61, and 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiore 3,421,509 in view of Szabo 5,325,846 further in view of Takahashi 5,050,585.

22. With respect to claims 52-55, 60, and 65-66, Fiore '509 in view of Szabo discloses the invention as discussed above.

23. However, Fiore '509 in view of Szabo fails to positively disclose the flexible sleeve being inflated while the endoscope is advanced through the transit passage, Wherein the flexible sleeve being inflated being deflated while the endoscope is retracted proximally through the transit passage, wherein the dispenser comprises a channel communicating with the flexible sleeve for inflating the flexible sleeve while the endoscope is advanced and for applying suction to the flexible sleeve while the endoscope is retracted, wherein the entry port fits snugly around the endoscope to prevent escape of pressure through the entry port when the flexible sleeve is inflated.

24. Takahashi teaches an analogous apparatus for sheathing an endoscope comprising a flexible sleeve 10a that is inflated while an endoscope is advanced through a transit passage (col. 4, lines 14-19). Takahashi further teaches a dispenser comprising a channel 11b contained within the insertion tube 1,9 an endoscope communicating with a sleeve via 21, for inflating the sleeve while the endoscope is advanced and for applying suction to the sleeve while the endoscope is retracted via 21 (col. 3, lines 60-61), resulting in an improved and practical sheathed endoscope having an a flexible structure which is capable of stably retaining therein a channel tube and which can readily be produced (col. 1, lines 65-68).

25. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the endoscope draping system of Fiore '509 in view of Szabo with the above discussed limitations as taught by Takahashi in order to have provided an improved and practical sheathed endoscope having an a flexible structure which is capable of stably retaining therein a channel tube and which can readily be produced, that facilitates the manipulation of the endoscope within a tortuous path of an internal organ of a patient.

26. With respect to the recitation "the sleeve is adapted to be deflated" in claim 53, since Takahashi teaches the sleeve 10a to be inflatable, then it would have been obvious to one ordinary skill in the art at the time of the invention that if a sleeve was adapted to be inflated, then it was also adapted to be deflated. With respect to the recitation "while the endoscope is retracted proximally through the transit passage" in claim 53, it would have been obvious to one ordinary skill in the art at the time of the invention to have deflated the sleeve upon retracting the endoscope through the transit passage in order to make it easier to withdraw.

27. With respect to the recitation “the entry port is adapted to fit snugly around the endoscope to prevent escape of pressure through the entry port when the flexible sleeve is inflated” in claim 55, it would have been obvious to one of ordinary skill in the art at the time of the invention to have sized the entry port such that when the flexible sleeve was inflated, the pressure exerted by the flexible sleeve on the entry port such that no liquid or fluid would be able to enter or exit the, since it has been held that, “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP 2144.05 II A).

28. With respect to the methods and steps recited in claims 65-66, where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

29. With respect to claim 61, Fiore '509 in view of Szabo in view of Takahashi discloses the invention as discussed above. Fiore '509 further teaches a channel 24 is contained within the dispenser 20,32 alongside the insertion tube 11,11'.

30. Claims 57 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiore 3,421,509 in view of Szabo 5,325,846 further in view of Carrillo, Jr. 6,663,598.

31. Fiore '509 in view of Szabo discloses the invention as discussed above. However, Fiore '509 in view of Szabo fails to positively disclose a sealing element sealing the proximal extremity of the working channel while the endoscope is removed from the dispenser.

32. Carrillo teaches a sealing element 10 for an endoscope which is capable of sealing the proximal extremity of a working channel while the endoscope is removed from a dispenser (col. 3, lines 51-54), resulting in an improved endoscope seal that effectively inhibits the egress of fluid from the working channel of an endoscope when an elongate device, having a non-circular shaft is disposed therein (col. 2, lines 14-17).

33. It would have been obvious to one ordinary skill in the art at the time of the invention to have provided the endoscope draping system of Fiore '509 in view of Szabo with the above discussed limitations as taught by Carrillo, Jr. in order to have provided an improved endoscope seal that effectively inhibits the egress of fluid from the working channel of an endoscope when an elongate device, having a non-circular shaft is disposed therein, facilitating a clean and sterile environment outside of the patient's body during surgery.

34. With respect to the methods and steps recited in claim 68, where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

35. Claims 58, 59, 69, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiore 3,421,509 in view of Szabo 5,325,846 further in view of Wilk 5,746,694.

36. Fiore '509 in view of Szabo discloses the invention as discussed above. However, Fiore '509 in view of Szabo fails to positively disclose the endoscope includes a working channel having distal and proximal outlets, and wherein the apparatus comprises an internal sleeve inserted through the working channel, the internal sleeve comprising distal and proximal

extremities, wherein the distal extremity being fixed to the distal end of the sleeve and the proximal extremity protruding from the proximal outlet of the working channel. Fiore '509 in view of Szabo also fails to positively disclose a sealing element sealing the proximal extremity of the internal sleeve while the endoscope is removed from the dispenser.

37. Wilk teaches an analogous endoscope draping system comprising an endoscope 16 that includes a working channel 40 having distal 20 and proximal outlets 18, and wherein the apparatus comprises an internal sleeve 10 inserted through the working channel 40, the internal sleeve 10 comprising distal 28 and proximal 26 extremities, wherein the distal extremity 28 being fixed to the distal end of the sleeve 10 and the proximal extremity 26 protruding from the proximal outlet 18 of the working channel 40 (figs. 2A,2B). Wilk also teaches a sealing element 32 sealing the proximal extremity of the internal sleeve 10 while the endoscope 14 is removed from the dispenser (figs. 2A,2B, col. 5, lines 20-67, col. 6, lines 1-67), resulting in an improved device for promoting cleanliness in endoscopic surgery while reducing the time spent on procedures to clean endoscopes.

38. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the endoscopy draping system of Fiore '509 in view of Szabo with the above discussed limitations as taught by Wilk in order to have provided an improved sheathed endoscope for promoting cleanliness in endoscopic surgery while reducing the time spent on procedures to clean endoscopes, facilitating an efficient and economical pre and post surgical processes and procedures.

39. With respect to the methods and steps recited in claims 69 and 70, where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired

and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

Response to Amendment

40. The cancellation of claims 1-47 and the addition of new claims 48-69 (now claims 48-70 as renumbered by the examiner), in the response filed on January 30th, 2008, is acknowledged.
41. Renumbered claims 48-70 are now pending in the application.

Response to Arguments

42. Applicant's arguments with respect to claims 1-47 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

43. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALIREZA NIA whose telephone number is (571)270-3076. The examiner can normally be reached on Mo.-Fri.-7:30 AM-5:00 PM EST-Alternate Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. N./
Examiner, Art Unit 3739
Alireza Nia
May 20th, 2008

/Linda C Dvorak/
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